MAY 1 4 2001

510 (k) SUMMARY

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21CFR § 807.92

The assigned 510(k) number is K010519

Submitted by: C. Kenneth French
President
Scion Valley, Inc.
Hwy. 6, North
Meridian, Texas 76665

Telephone #: 254-435-2306
Facsimile #: 254-435-2226

Date Prepared: 19 January 2001

Establishment Registration Number:	Scion Valley, Inc. is located at Hwy. 6, North in Meridian, Texas 76665. We are registered with the Food and Drug Administration as Establishment Number 1645369.
Classification Name:	Endoscope and Accessories Gynecologic Laparoscope and Accessories
Common/Usual Name:	MAGNUM FLOW IRRIGATION SYSTEM
Proprietary Name:	No Proprietary Name has been selected for this product as of the time of the 510(k) submission.
Indication for Use:	The MAGNUM FLOW IRRIGATION SYSTEM is designed to be used in conjunction with a laprascopic probe handle and tip to provide controlled powered irrigation/aspiration during general laprascopic and gynological and obstetrical laprascopic surgical procedures. It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage. The Magnum Flow Irrigation System is designed for single patient use. Not intended for reuse.
Device Description:	The Candidate Device uses a mechanical pumping system to generate fluid output. It is powered with eight (8) standard AA alkaline batteries with an output amperage of approximately 1.0 ampere, with a voltage of 12 volts, direct current (dc). The batteries power a motor, which activates movement of an impeller pump which drives the irrigation fluid to a preattached irrigation valve irrigation probe for delivery to the operative site. The proposed MAGNUM FLOW IRRIGATION SYSTEM is designed for single patient use. The flow rate of fluid delivered by the system is variable, by design, between 0-2.5 liters a minute. Maximum flow rate is dependent on the probe tip size. Following completion of the procedure, the batteries, which power the pump are to be removed for proper disposal.

Substantial Equivalence Claim:

The principles of operation and technology in the Scion Valley, Inc. MAGNUM FLOW IRRIGATION SYSTEM are similar to other devices such as the Hydro-Surg Lapraroscopic Irrigator which the FDA has found to be substantially equivalent to preamendment devices as outlined below:

Product:	Hydro-Surg Laparoscopic Irrigator
Manufacturer:	Davol Inc.
510(k) Number:	K961492
Substantial Equivalence Date:	15 May 1996

Product:	Bard Laparoscopic Irrigator Pump System
Manufacturer:	Davol Inc.
510(k) Number:	K902722
Substantial Equivalence Date:	16 November 1990

- end of summary-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2001

Mr. C. Kenneth French
President
Scion Valley, Inc.
Highway 6, North
Meridian, Texas 76665

Re: K010519
Trade/Device Name: Magnum Flow Irrigation System
Regulation Number: 876.1500
884.1720
Regulatory Class: II
Product Code: GCJ, HET
Dated: January 19, 2001
Received: February 22, 2001

Dear Mr. French:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K010519

Device Name: MAGNUM FLOW IRRIGATION SYSTEM

Indications for Use:

The MAGNUM FLOW IRRIGATION SYSTEM is designed to be used in conjunction with a laprascopic probe handle and tip to provide controlled powered irrigation/aspiration during general laprascopic and gynological and obstetrical laprascopic surgical procedures. It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage. The MAGNUM FLOW IRRIGATION SYSTEM is designed for single patient use. Not intended for reuse.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Over-the-Counter
(Optional format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010519